4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1118]

Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)." This guidance identifies the key features of non-clinical and clinical investigational plans used to support investigational device exemption applications, premarket approval applications, De Novo classification requests, and some premarket notification submissions for devices used in the treatment of BPH.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-D-1118 for "Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy,

including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Charles Viviano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2680, Silver Spring, MD 20993-0002, 240-402-2975.

SUPPLEMENTARY INFORMATION:

I. Background

As men age, the prostate enlarges over time, obstructing the prostatic urethra and resulting in anatomic and functional changes in the bladder. The resulting condition, known as benign prostatic hyperplasia (BPH), can be associated with decreased peak urinary flow rate and increased post void residual urine. Men with BPH experience bothersome lower urinary tract symptoms that affect their quality of life by disrupting sleep patterns or interfering with daily activities.

This guidance revises the guidance entitled "Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)[1]," issued on August 17, 2010 ("2010 BPH guidance"). This guidance identifies the key features of non-clinical and clinical investigational plans used to support investigational device exemption applications, premarket approval applications, De Novo classification requests, and some premarket notification submissions for devices used in the treatment of BPH. Some recommendations in this document may not apply to a particular device, and additional recommendations may be appropriate for novel device types or technologies. FDA will consider alternative non-clinical and clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

FDA issued a draft guidance entitled "Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia

[1] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-non-clinical-and-clinical-investigation-devices-used-treatment-benign-prostatic-hyperplasia.

(BPH)[2]," which proposed to add new devices within scope and updates to the animal and clinical studies sections of the 2010 BPH guidance. A notice of availability of the draft guidance appeared in the *Federal Register* of July 14, 2020 (85 FR 42406). FDA considered comments received and revised the guidance as appropriate in response to the comments, including the following technical changes: suggested examination of surrounding anatomy during animal studies for embolic devices; clarification of sexual function; additional specificity around the primary safety endpoint; inclusion of secondary endpoints such as return to normal activities; measuring prostate volume according to current clinical guidelines; additional post-treatment evaluation; and consideration of the addition or increase in medications or other modalities as treatment failure. The remainder of the content of the 2010 BPH guidance remains largely unchanged.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on non-clinical and clinical investigation of devices used for the treatment of BPH. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov and at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of "Non-Clinical and

[2] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-guidance-non-clinical-and-clinical-investigation-devices-used-treatment-benign.

Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1724 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
812	Investigational Device Exemption	0910-0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)"	De Novo classification process	0910-0844
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"	Q-submissions	0910-0756
800, 801, and 809	Medical Device Labeling Regulations	0910-0485
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910-0755
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910-0119

Dated: December 20, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-27919 Filed: 12/23/2021 8:45 am; Publication Date: 12/27/2021]